(DL) DRAFT

SUMMARY OF FDA REGULATORY AUTHORITY AND THE PROPOSED TOBACCO REGULATIONS

President Clinton announced August 10, 1995 that he decided to permit FDA Commissioner Kessler to begin the process of asserting jurisdiction over cigarettes. On August 11, FDA published proposed regulations as part of its Rule Making process; a 90 day public comment period has begun. The proposed regulations, purportedly designed to limit youth access to cigarettes, are misguided and contrary to federal law. Only Congress can change the law to give FDA the authority to regulate cigarettes -- and that has not happened.

Philip Morris believes minors should not smoke and should not have access to cigarettes -- a conviction we share with all Americans -- and we have a long history of supporting measures, voluntary and legislative, directed at preventing youth from acquiring cigarettes. As part of our recently announced Action Against Access initiative, we are committed to continuing our efforts unilaterally, and working with other members of the industry, the nation's retailers and legislators to ensure that effective barriers are placed to block youths who attempt to buy cigarettes. The best way to keep cigarettes from kids is to keep kids from cigarettes.

I. FDA REGULATORY AUTHORITY AND CIGARETTES

FDA is the agency charged with overseeing the safety of the nation's food, drugs and medical devices. Under Federal law, the FDA can regulate products as "drugs" or "devices" only if they are "intended for use in the . . . treatment or prevention of disease in man . . . [or] . . . [intended] to affect the structure or function of the body of man."

For more than 80 years, FDA and its predecessor agencies have informed Congress that cigarettes do not meet the criteria for regulation by FDA under existing federal law and Congress has agreed. In amending the Federal Food, Drug and Cosmetic Act nearly 70 times, Congress has never given the FDA jurisdiction over tobacco. In fact, on 20 occasions, Congress has failed to pass legislation that would have granted FDA jurisdiction over the tobacco industry.

Nine federal government agencies, including the Federal Trade Commission and the Department of Justice, oversee various facets of the tobacco industry. But in each of those cases, oversight has been granted by Congress. Congress has never delegated the authority to regulate cigarettes to the FDA. Though Commissioner Kessler has tried to "create" FDA jurisdiction by raising the issue of youth smoking, his stated desire to reduce youth access to tobacco cannot create jurisdiction where none exists.

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II. SPECIFIC ELEMENTS OF FDA S PROPOSED TOBACCO REGULATIONS

Primary elements of the proposal include the following:

1) Creates a minimum age requirement for cigarette sales of 18 years of age. (This is urrently the law in all states; two states have minimum age laws of 19.)

2) Requires retailer age identification of buyers who do not appear to be at least 26 years old and mandates removal of self-service displays. Ads at retail outlets (point of sale), are restricted to black and white text only (tombstone).

3) Prohibits cigarette packs with fewer than 20 cigarettes and prohibits single cigarette sales. Agency is also considering establishing a maximum number of cigarettes per pack.

4) Bans all vending machines.

5) Prohibits all product sampling and mail order sales/redemption of mail order coupons.

6) Prohibits cigarette brand sponsorship of any athletic, musical, artistic, or other social or cultural event; use of corporate names is permitted.

7) Prohibits sale or distribution of all cigarette brand identifiable non-tobacco items and services, e.g. hats, shirts, bags.

8) Bans billboards within 1000 feet of an elementary or secondary school, or playground. All other billboard advertising is restricted to black and white text only.

9) Prohibits brand image advertising in publications with a set percentage of youth readership; permits only black and white text ads in such publications. Brand image ads could appear only in adult newspapers, magazines, periodicals, or other publications.

10) In all, the products name advertisements must be followed by the words "A Nicotine - Delivery Device" and additional warnings addressed to minors are required.

11) Requires each manufacturer to establish and maintain a national public educational program to combat the effect of cigarette advertising. Requires annual expenditures of $150 million, allocated proportionately to a company's share of total industry advertising and promotional expenditures.

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III. CONCLUSION

Having opted to pursue more federal regulation, the Administration has ensured that the more effective and expedient course of cooperative action takes second place to those who want to expand the federal bureaucracy and its unwanted intrusion into the private lives of adult Americans.

The Administration's decision is all the more troubling in light of the fact that several weeks ago, Philip Morris committed itself to a comprehensive program, Action Against Access, designed to prevent kids from obtaining cigarettes by any legal means.

Packs and cartons of Philip Morris U.S.A. cigarettes are now being produced bearing the new notice: "Underage Sale Prohibited." These will be on the retail shelves by fall.

Philip Morris U.S.A. has already discontinued free cigarette sampling to consumers and distribution of cigarettes through the mail in the United States.

Philip Morris U.S.A. is implementing programs to deny merchandising benefits and participation in our retail incentive programs to stores fined for or convicted of selling cigarettes to minors. We are working to place minimum age of purchase signage in over 200,000 retail outlets around the country, and we are working on education and compliance seminars for retailers and law enforcement officials. We also are increasing our already aggressive efforts to prevent the use of our cigarette brand names or logos on any item marketed to minors, including video games and toys.

These are actions we have been able to undertake on our own. Working with retailers, state policy makers, law enforcement officials and others throughout the United States, we are committed to the enactment of reasonable state legislation to license all retailers who sell cigarettes, accompanied by enforcement mechanisms, notification procedures and sanctions for violations. We are also supporting enactment of state legislation to prevent purchase of cigarettes by minors from vending machines; state legislation to ensure that all cigarettes at retail are in sight of or under the control of a sales clerk; and the mandatory posting of minimum age signage.

Unlike FDA regulation, these are among the legitimate (or lawful) ways to deal with the challenge of youth smoking.

If the goal is to prevent the sale of cigarettes to minors, we believe common-sense approaches will work best. As we said when we announced our program on youth access, the best way to keep kids away from cigarettes is to keep cigarettes away from kids.

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